

§IN THE UNITED STATES PATENT AND TRADEMARK OF

icant(s)

Jose Gutierrez-Rocca et al.

Serial No.

10/086,059

For

A SUSTAINED RELEASE

PHARMACEUTICAL FORMULATION

Filed

February 27, 2002

Group Art Unit

1617

Examiner

Theodore J. Criares

745 Fifth Avenue New York, NY 10151

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop AF Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on 2003.

erome Rosenstock, Reg. No.

ant, Assignee or Regi

Date of Signature

RESPONSE UNDER 37 CFR § 1.111

Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA. 22313-1450

Sir:

This is in response to the Office Acton mailed on June 30, 2003.

Claims 1 through 16 are presently in the subject application.

Enclosed is a copy of the subject application as filed ("COPY"). The undersigned,

Jerome Rosenstock, herein certifies that the COPY is a true copy of the subject application as

filed. Accordingly there was an original claim 10. Restriction has been required under 35

U.S.C. § 121, as follows,

GROUP I Drawn to compositions to prolonged release formulations, comprising original claims 1 through 8, and 11-12 of the COPY; and

GROUP II Drawn to processes for the preparation of sustained/prolonged release formulations, comprising original claims 9-10 and 13-16 of the COPY.

In view of the mandatory requirements of 35 U.S.C. § 121, Applicant provisionally elects **GROUP I**, comprising original claims 1-8 and 11-12 of the COPY, with traverse.

Favorable reconsideration and withdrawal of the requirement for restriction, particularly the restriction among GROUPS I and II, is requested. It is believed that a proper search to determine the patentability of the compositions of prolonged release formulations of claims 1-8 and 11-12 of the COPY would include the process for the preparation of these formulations, as defined in claims 9-10 and 13-16.

The Examiner's requirement for restriction was made pursuant to the provisions of the MPEP § 806.05(e). Applicant kindly refers the Examiner to a provision of the MPEP § 803, which provides that:

If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

In the present case it is courteously submitted that an examination of the entire application and all of the claims can be made without serious burden. The Examiner will have to study Applicant's entire specification in connection with his examination of the elected invention. No additional effort will be required to study the specification with respect to the remaining claims.

Accordingly, withdrawal of the restriction requirement is respectfully requested.

The Examiner is hereby authorized to call the undersigned attorney of record "collect' on any matter connected with this application. The telephone number is 212-588-0800. In the absence of the undersigned attorney of record, the call will be accepted by any attorney empowered in this application.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By:_

berome Rosenstock

Attorney for Applicants Registration No. 25,456

(212) 588-0800

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UTILITY PATENT APPLICATION TRANSMITTAL

Attorney Docket No.		540591-7095.1					
First Inventor		Jose Gutierrez-Rocca					
Title	A SUSTAINED	RELEASE PHARMACEUTICAL FORMULATION					
Express Mail Label No.		EL 819167707 US					

(Only for new nonprovisional applications under 37 CFR 1.53(b))

APPLICATION ELEMENTS	Assistant Commissioner for Patents						
See MPEP chapter 600 concerning utility patent application contents.	ADDRESS TO: Box Patent Application Washington, DC 20231						
1. Fee Transmittal Form (e.g., PTO/SB/17) (Submit an original, and a duplicate for fee processing) 2. Applicant claims small entity status. See 37 CFR 1.27. 3. Specification [Total Pages 18] (preferred arrangement set forth below) - Descriptive title of the invention - Cross References to Related Applications - Statement Regarding Fed sponsored R & D - Reference to sequence listing, a table, or a computer program listing appendix.	7. CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix) 8. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary) a. Computer Readable Form (CFR) b. Specification sequence Listing on: i. CD-ROM or CD-R (2 copies); or ii. paper						
- Background of the Invention	c Statements verifying identity of above copies ACCOMPANYING APPLICATION PARTS						
 Brief Summary of the Invention Brief Description of the Drawings (if filed) Detailed Description Claim(s) Abstract of the Disclosure 	9. Assignment Papers (cover sheet & documents(s)) 10. 37 CFR 3.73(b) Statement Power of Attorney						
4. Drawing(s)(35 U.S.C. 113) [Total Sheets]	(when there is an assignee) 11 Finalish Translation Document (if applicable)						
5. Oath or Declaration [Total Pages] a. Newly executed (original or copy) b. Copy from a prior application (37 CFR 1.63(d)) (for continuation/divisional with Box 18 completed) i. DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b). 6. Application Data Sheet. See 37 CFR 1.76. 18. If a CONTINUING APPLICATION, check appropriate box, and in an Application Data Sheet under 37 CFR 1.76: Continuation Divisional Continuation-in Prior application information: Examiner: For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of Box 5b, is considered a part of the disclosure of the accompanying continuation	Group/Art Unit: the prior application, from which an oath or declaration is supplied under or divisional application and is hereby incorporated by reference.						
The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts. 19. CORRESPONDENCE ADDRESS							
Customer Number or Bar Code Label (Insert Customer No. or Attach bar code label for Correspondence address below							
Name	1						
Name (Print/Type) JEROME ROSENSTOCK, ESO. R Signature Loone Weenth	stration No. (Attorney/Agent) 25,456 Date February 27, 2002						

Approved for use through 10/31/2002. OMB 0651-0032 and Trademark Office; U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL for FY 2001

Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT

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Application Number		\dashv				
Filing Date		\dashv				
First Named Inventor	Jose Gutierrez-Rocca	7				
Examiner Name		٦				
Group/Art Unit		٦				
Attorney Docket No.	540591-7095-1	7				

METHOD OF PAYMENT					FEE CALCULATION						
The Commissioner is hereby authorized to charge				charge	-3. ADDITIONAL-FEES						
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Account Number	Account 50-0320 Number				127	50	227	25		ge – late provisional filing fee wer sheet	
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Under 37 C	Under 37 CFR 1.16 and 1.17 . In oat the Mailing of the Notice of Allowance					920*	112	920*		ting publication of SIR prior to iner action	
2. Payment Enclosed					113	1,840*	113	1,840*		ting publication of SIR after niner action	
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					117	920	217	460	Extensio	n for reply within third month	
1. BASIC F	ILING FEE				118	1,440	218	720		n for reply within fourth	
Large Ent	•	Entity			128	1,960	228	980		n for reply within fifth month	
Fee Fe Code (\$		Fee (\$)	Fee Description	Fee Paid	119	320	219	160	Notice of	Appeal	
101 74			Utility filing fee	740.00	120	320	220	160		orief in support of an appeal	
106 33			Design filing fee		121	280	221	140		for oral hearing	
107 510 108 740	208		Plant filing fee Reissue filing fee		138	1,510	138	1,510	Petition t Proce	o institute a public use eding	
114 160	214		Provisional filing fee		140	110	240	55	Petition t	o revive – unavoidable	
l		20B1	OTAL (1)	740.00	141	1,280	241	640	Petition to	o revive- unintentional	
	·				142	1,280	242	640	Utility iss	ue fee (or reissue)	
2. EXTRA C	LAIM FEES	3			143	460	243	230	Design is	sue fee	
		Extra Claim	Fee from below	Fee Paid	144	620	244	310	Plant issu	ue fee	
Total Claims 16	-20** =	0 X	18	= 0.00	122	130	122	130	Petitions	to the Commissioner	
Ind. Claims 6	-3** =	3 X	84	= 252.00	123	50	123	50	Petitions Applica	related to provisional ations	
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** or	number previo	usly paid, if gre	ater; for reissues,	see below	581	40	581	40		g each patent assignment per ly (times number of properties)	
Large Entit		Entity			146	740	246	370	Filing a se	ubmission after final rejection	
Code (\$)		Fee (\$)	Fee Desc	cription	149	740	249	370		R 1.129(a)) additional invention to be	
103 18	203	9	Claims in excess of	20	1,75	140	243	370	examin	ed (37 CFR 1.129(b))	
102 84	202		Independent claims		i					_	
104 280		140	Multiple dependent	claim, if not paid	Other fee (s	specify)	_				
109 84	209	42 ** Reissue independent claims over original patent		Other fee (s	pecify)				:		
110 18	210		Reissue claims in ex over original patent				•				
107 510	207	255	Plant filing fee			•					
		SUBTO	OTAL (2)	(\$)252.00						SUBTOTAL (3)	(\$)0.00
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SUBMITTED BY Typed or Printed Name JEROME ROSENSTOCK				1/					Complete (if applicable		
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CERTIFICATE OF MAILING – SEPARATE PAPER

Attorney Docket No.:

540591-7095.1

Serial No.

Not Yet Known

Filed

Herewith

Applicant(s)

Jose Gutierrez-Rocca

Date of Deposit 02/27/02 via "Express Mail" #EL 819167707 US

I hereby certify that a Provisional Patent Application and related documents for the above-referenced application are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to:

Assistant Commissioner for Patents Washington, D.C. 20231

(Typed or printed name of person mailing paper or fee)

(Signature of person mailing paper or fee)